

(c) *Related tolerances.* See § 556.150 of this chapter.

(d) *National Academy of Sciences/National Research Council NAS/NRC status.* The conditions of use specified in this section were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter but may require bioequivalency and safety information.

(e) *Conditions of use. Calves—(1) Amount.* One 250 milligram bolus per 50 pounds of body weight twice a day for 3 to 5 days.

(i) *Indications for use.* Treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* spp., *Klebsiella* spp., and *Hemophilus* spp.

(ii) *Limitations.* Administer bolus directly by mouth or crush and dissolve in milk or water for drenching or bucket feeding; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.

(2) *Amount.* One 25 milligram tablet for each 5 pounds of body weight every 12 hours daily for 3 to 5 days.

(i) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia associated with *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.

(ii) *Limitations.* Administer tablet directly by mouth or crush and dissolve in water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; when feeding milk or milk replacer, administration 1 hour before or 2 hours after feeding; do not administer within 24 hours of slaughter.

(3) *Amount.* One 500 milligram bolus per 100 pounds of body weight twice a day for 3 to 5 days.

(i) *Indications for use.* Treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.

(ii) *Limitations.* Administer directly by mouth or crush and dissolve in

water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.

[57 FR 37325, Aug. 18, 1992, as amended at 67 FR 78355, Dec. 24, 2002]

#### § 520.446 Clindamycin capsules and tablets.

(a) *Specifications—(1)* Each capsule contains the equivalent of 25, 75, 150, or 300 milligrams (mg) clindamycin as the hydrochloride salt.

(2) Each tablet contains the equivalent of 25, 75, or 150 mg clindamycin as the hydrochloride salt.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter as follows:

(1) Nos. 000009 and 059130 for use of capsules described in paragraph (a)(1) of this section as in paragraphs (d)(1)(i) and (d)(2)(i) of this section.

(2) No. 051311 for use of tablets described in paragraph (a)(2) of this section as in paragraphs (d)(1)(ii) and (d)(2)(ii) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use in dogs—(1) Amount—(i)* Wounds, abscesses, and dental infections: 2.5 to 15 mg per pound (lb) of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 to 15 mg/lb of body weight every 12 hours for a minimum of 28 days.

(ii) Wounds, abscesses, and dental infections: 2.5 mg/lb of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 mg/lb of body weight every 12 hours for a minimum of 28 days.

(2) *Indications for use—(i)* For the treatment of skin infections (wounds and abscesses) due to susceptible strains of coagulase-positive staphylococci (*Staphylococcus aureus* or *S. intermedius*), deep wounds and abscesses due to susceptible strains of *Bacteroides fragilis*, *Prevotella melaninogenica*, *Fusobacterium necrophorum*, and *Clostridium perfringens*, dental infections due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenica*, *F. necrophorum*, and *C. perfringens*, and osteomyelitis due to susceptible strains

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of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*.

(ii) For the treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible strains of *S. aureus*, soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*.

[67 FR 54954, Aug. 27, 2002, as amended at 68 FR 55824, Sept. 29, 2003; 69 FR 32273, June 9, 2004]

## § 520.447 Clindamycin liquid.

(a) *Specifications*. Each milliliter of solution contains the equivalent of 25 milligrams (mg) clindamycin as the hydrochloride salt.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter as follows:

(1) Nos. 000009 and 059130 for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii)(A), (d)(2)(i)(A), and (d)(2)(ii)(A) of this section.

(2) No. 059079 for use as in paragraphs (d)(1)(i)(B), (d)(1)(ii)(B), (d)(2)(i)(B), and (d)(2)(ii)(B) of this section.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*—(A) Wounds, abscesses, and dental infections: 2.5 to 15 mg per pound (lb) of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 to 15 mg/lb of body weight every 12 hours for a minimum of 28 days.

(B) Wounds, abscesses, and dental infections: 2.5 mg per pound (lb) of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 mg/lb of body weight every 12 hours for a minimum of 28 days.

(ii) *Indications for use*—(A) For the treatment of skin infections (wounds and abscesses) due to susceptible strains of coagulase-positive staphylococci (*Staphylococcus aureus* or *S. intermedius*), deep wounds and abscesses due to susceptible strains of *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens*, dental infections due to

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susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*, and osteomyelitis due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*.

(B) For the treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible strains of *S. aureus* and for soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*.

(2) *Cats*—(i) *Amount*—(A) 5.0 to 15.0 mg/lb of body weight every 24 hours for a maximum of 14 days.

(B) 5.0 to 10.0 mg/lb of body weight every 24 hours for a maximum of 14 days.

(ii) *Indications for use*—(A) For the treatment of skin infections (wounds and abscesses) due to susceptible strains of *S. aureus*, *S. intermedius*, *Streptococcus* spp., deep wounds and abscesses due to susceptible strains of *Clostridium perfringens* and *Bacteroides fragilis*, and dental infections due to susceptible strains of *S. aureus*, *S. intermedius*, *Streptococcus* spp., *C. perfringens*, and *B. fragilis*.

(B) *Aerobic bacteria*: Treatment of soft tissue infections (wounds and abscesses) and dental infections caused by or associated with susceptible strains of *S. aureus*, *S. intermedius*, and *Streptococcus* spp. *Anaerobic bacteria*: Treatment of soft tissue infections (deep wounds and abscesses) and dental infections caused by or associated with susceptible strains of *C. perfringens* and *B. fragilis*.

[67 FR 54954, Aug. 27, 2002, as amended at 67 FR 78684, Dec. 26, 2002; 68 FR 55824, Sept. 29, 2003; 69 FR 31734, June 7, 2004]

## § 520.452 Clenbuterol syrup.

(a) *Specifications*. Each milliliter contains 72.5 micrograms of clenbuterol hydrochloride.

(b) *Sponsor*. See 000010 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. Administer orally twice a day (b.i.d.). Initial dose is 0.5 milliliter per